ANS

November 3, 2000

Documents Management Branch (HFA-305)
Food and Drug Administration
5630 Fisher Lane Room 1061
Rockville, MD 20852

Re: FDA Docket Number: 00P-0788
Reclassification of the Totally Implanted Spinal Cord Stimulator

To Whom It May Concern:

Today, Advanced Neuromodulation Systems, Inc. ("ANS") obtained from the above-referenced public docket file copies of the August 14, 2000 letter from Medtronic attaching copies of the overheads used during its July 27, 2000 meeting with numerous representatives of the Center for Devices and Radiological Health ("CDRH").

In part, Medtronic relied on "Five Major Points" in its effort to "Discuss the inappropriateness of reclassification of IPGs into Class II." Of course, ANS believes it was inappropriate for Medtronic to schedule this meeting, because it had three (3) prior opportunities to express its views as part of a public administrative process. ANS does not believe it is necessary to address the cryptic description of these five points, because comments addressing these points are presently part of the public record. However, we do believe it is appropriate to comment on the December 29, 1995 letter Medtronic provided to CDRH representatives and which Medtronic has identified in the past.

For reference purposes, I have attached a copy of the letter provided by Medtronic (Exhibit A) along with the enclosure, which was not provided by Medtronic (Exhibit B). Because ANS does not have a copy of the November 22, 1995 letter, it cannot comment on the

, INC.
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motivation for this letter or why it was not received until December 20, 1995 but responded to only nine days later.

The third paragraph of the December 29, 1995 letter references "significant technological differences," yet the example provided is clearly erroneous. The Class II device identified in 21 C.F.R. § 882.5880 does contain active implantable components, because the receiver to which lead electrodes are attached is implanted as part of the surgical procedure. It is true that necessary energy is provided by an external power source, but in no way can the implanted receiver electrode combination be characterized as "passive."

The partially implanted spinal cord system ("SCS") currently manufactured by ANS has been in commercial distribution since 1981. The difference between the implantable pulse generator ("IPG") and RF device is the placement of the power source, an option that the physician and patient can exercise.

In 1980 when Medtronic sought to market its IPG device through the premarket notification process (See Exhibit B), ANS believes that its position was correct and that the partially implanted and totally implanted devices were substantially equivalent for the intended use. Medtronic had the opportunity then and at any time since then to petition for reclassification. The company did not elect to do so and, therefore, has been able to maintain a virtual monopoly for more than a decade.

At the time that Medtronic received its premarket approval, the Food and Drug Administration ("FDA") did not have authority to issue an order in response to a premarket, 510(k), notification or to impose special controls. Moreover it could not require user facility reporting, design controls, recall, postmarket surveillance, civil penalties, and a variety of other options to provide reasonable assurance of device safety and effectiveness. These pervasive requirements and additional regulatory flexibility occurred as a result of significant changes to law in 1990, 1992, 1997.

ANS is confident that it can satisfy the Class II special controls applied by the CDRH for issuance of a clearance order. More important, we have great confidence that the devices ANS makes available to patients will be safe and effective for the intended use consistent with the state of the art. Medtronic need not fear the prospect of competition and should reflect on its own history as an entrepreneurial business. The cardiac pacemakers it developed, manufactured, and distributed were made available to physicians without any state or federal government

preclearance. Its standing in a competitive market place was determined by its ability to satisfy the health care community.

Like Medtronic and every responsible device manufacturer, ANS is committed to developing, manufacturing, and distributing the safest and most effective devices possible. It respects the responsibility of the FDA and believes that FDA discharge of this responsibility is adequate to provide reasonable assurance of safety and effectiveness of a Class II IPG device.

Sincerely,

Drew Johnson

Director, Regulatory Affairs

Enclosures

cc: Dr. D. Feigal
Celia Witten
Russ Pagano
Nancy Pluhowski
Heather Rosecrans
Marjorie Shulman
Joseph Sheehan
Kristen Bowsher

DEPARTMENT OF HEALTH & HUMAN SERVICES - Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 29 1995

Mr. Robert J. Klepinski
Senior Legal Counsel
Medtronic, Inc.
Law Department
7000 Central Avenue, NE
Minneapolis, Minnesota 55432-3576

Re: C950010 -- Classification of Medtronic Itrel™
Dated: November 22, 1995
Received: December 20, 1995

Dear Mr. Klepinski:

This is response to your request to Mr. Fred Sadler for classification information dated November 22, 1995. The Medtronic Itrel™ Totally Implantable Spinal Cord System was determined by PDA to be a class III device by order dated October 29, 1980, (copy enclosed). The Food and Drug Administration (FDA) determined that the Medtronic Totally Implantable Spinal Cord System was not substantially equivalent to any device marketed prior to May 28, 1976, or to any device classified as a class I or class II device; therefore it could not be marketed until FDA approved a premarket approval application in accordance with Section 513(f) of the Federal Food, Drug, and Cosmetic Act.

As specified by Section 513(f) of the Food, Drug, and Cosmetic Act (act), a device to be marketed after May 28, 1976, is classified into class III unless the FDA determines the device to be substantially equivalent to a preamendments device, or the device is reclassified into class I or class II.

FDA determined that this Medtronic device was not substantially equivalent to devices classified in Title 21, Code of Federal Regulations, Section 882.5880 (21 CFR 882.5880) based on significant technological differences. For example, the Medtronic device employs an implanted device containing a power source; whereas, the devices classified in 21 CFR 882.5880 employs an implanted device comprised entirely of passive components with necessary energy being provided by an external device.

As further evidence of this determination, FDA sent to Medtronic, Inc. on August 2, 1989, an order approving the Premarket Approval Application (PMA) for the Medtronic Itrel II™, which includes a Model 7424 Implantable Pulse Generator and a Model 7496 Quadrapolar Extension.

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We believe this unequivocally establishes that Medtronic Totally Implantable Spinal Cord System is by statute a class III device for which an approved PMA is required for marketing. If you have further questions, please contact Robert F. Munzner, Ph.D., at (301) 443-8517.

Sincerely yours,

Susan Alpert, Ph.D., M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
SILVER SPRING, MD. 20910

(B)

OCT 29 1980

Mr. Russell W. Felkey
Sr. Product Regulation Manager
Medtronic, Inc.
3055 Old Highway Eight
P.O. Box 1453
Minneapolis, MN 55440

Re: K802514 - Medtronic Totally Implantable Spinal Cord Stimulation System

Dear Mr. Felkey:

The Food and Drug Administration (FDA) has completed its review of your premarket notification submission K802514 under Section 510(k) of the Federal Food, Drug, and Cosmetic Act.

Based upon our review, we have concluded that the Medtronic Totally Implantable Spinal Cord Stimulation System is not substantially equivalent to any device that was in commercial distribution before May 28, 1976, or to any device introduced since that date which has been classified in Class I (General Controls) or Class II (Performance Standards). This decision is based on the fact that your design is based on a totally implanted device as compared to the R-F coupled principle employed in the design of the preenactment device, and also based on major differences in the electrical stimulation parameters being employed.

Therefore, your device is classified by statute in Class III (Premarket Approval), under section 513(f) of the Act.

Premarket Approval. Section 515(a)(2) of the Act requires Class III devices to have an approved premarket approval application before they can be legally marketed, unless the device is the subject of an investigational device exemption under Section 520(g) or unless the device has been reclassified.

To prepare a premarket approval application, statutory provisions appearing in Section 515(c) of the Act must be followed. Until regulations for premarket approval applications have been promulgated, we suggest you follow the pertinent parts of the regulations for new drug applications in 21 CFR, Part 314, as guidelines.

Investigational Use. In the absence of an approved premarket approval application, a Class III device may be distributed only for investigational use. Enclosed for your information, is the final regulation for investigational devices which was published in the Federal Register on January 18, 1980. We believe the regulations set forth desirable procedures and safeguards for the conduct of clinical investigations. The label for such devices must indicate that the devices are for investigational use only.

Petition for Reclassification. If you believe that your device should not have to undergo premarket approval before it is commercially distributed, you may petition FDA for reclassification of your device under section 513(f)(2) of the Act.

Premarket approval applications, investigational device exemption requests, and petitions for reclassification should be submitted to:

Food and Drug Administration
Bureau of Medical Devices
Document Control Center (HFK-20)
8757 Georgia Avenue
Silver Spring, Maryland 20910

Any commercial distribution of this device prior to approval of an application for premarket approval or the effective date of any order by the FDA reclassifying your device into Class I or II, would be a violation of the Federal Food, Drug, and Cosmetic Act.

Should you require any additional information concerning our decision or the alternatives available to you under the law, please contact:

James R. Veale
Director, Division of Anesthesiology
and Neurology Devices (HFK-430)
Bureau of Medical Devices

Sincerely yours,

Robert S. Kennedy

Robert S. Kennedy, Ph.D.
Associate Director for
Device Evaluation
Bureau of Medical Devices

Enclosure